

What is a Wearable Device? Lifestyle Device vs. Medical Device

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This article discusses how to determine when wearable lifestyle devices, referred to as fitness trackers, might be categorized as medical devices. In cases where fitness trackers are used in particular ways, their categorization as a medical device carries with it specific requirements for compliance to regulations. The article provides useful information to regulatory personnel in assessing how much compliance to the Health Insurance Privacy and Portability Act (HIPPA)¹ is expected for a wearable lifestyle device or fitness tracker with imbedded software when used for specific purposes. The article also reviews the migration from lifestyle device to medical device and the accompanying regulatory implications, including FDA's 'intended use.' The concept of "intended use" is key in making the distinction between lifestyle device and medical device, as in the case of wearable fitness devices.^{2,3}

Introduction

Ten or 15 years ago, the concept of a wearable medical device would probably bring to mind a diabetic insulin pump or a cochlear implant. Today, wearable lifestyle and medical devices are becoming more available to the average and generally healthy person. Fitness trackers are becoming more mainstream as well—to the point at which they are now addressed in lifestyle and health publications for the general public. *Science Daily* cited Technische Universität Darmstadt as reporting almost 20 million fitness trackers were sold worldwide in the first quarter of 2016, joining millions of others already in use.⁴

As the market grows for these devices, more manufacturers enter the market, each with unique features to attract buyers. In the span of one month, Fossil and TomTom both announced new fitness trackers. Fossil, long known as a watch maker, announced analog versions. The Fossil models track steps, distance, calories, sleep and include silent alarms to notify the wearer to smartphone notifications.⁵ TechCrunch.com reported TomTom was introducing three new fitness trackers; these models offer the typical fitness information coupled with robust GPS capabilities.⁶

The wearable device genre of fitness tracker is becoming increasingly focused on lifestyle and health rather than mere distances and steps. Other companies, including Jawbone, Fitbit, Samsung and Apple have all introduced their own wearable devices. As a multi-purpose device popular among all age groups, it is easy to see how manufacturers are aiming at health-related markets as well as those related to style, but in doing so, the expanding list of health-related features creates a different environment in which to view these wearable lifestyle devices.

What is a Medical Device?

According to FDA, a medical device is "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent or other similar or related article, including a component part or accessory which is:

- recognized in the official National Formulary or the United States Pharmacopoeia or any supplement to them
- intended for use in the diagnosis of disease or other conditions or in the cure, mitigation
- intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes.⁷

How do fitness trackers become viewed as medical devices?

The migration of fitness trackers and other wearable lifestyle devices to medical devices, in FDA's view, pivots on the concept of 'intended use.' This concept becomes the standard for assessing whether or not the fitness tracker and software are functioning as a medical device. Although somewhat simplistic, an accurate statement might be to say while the technology remains the same, what changes is the precise purpose for which the device is used. Because a medical device can be one used in the prevention of disease, a fitness tracker could potentially cross into that category when, for example, it is providing feedback to the diabetic or pre-diabetic wearer who is trying to lose weight in order to prevent or mitigate further degradation of his/her health. The fitness tracker also might be considered a medical device if by tracking the heart rate of the wearer, it is intended to provide information for treatment and perhaps to mitigate the possibility of a cardiac event. All of the above discussion relates to determining the official "indications for use" for the device, which is critical to FDA's determination if the tracker is a medical device and if so, under what regulations it should be processed. Since the fitness tracker is outside the body and does not involve chemical interventions, it fits into FDA's definition when used in these ways.

It has been reported wearable technologies have expanded markedly into medical devices, beginning with hearing aids through the use of the devices as heartbeat monitors and pain management.⁸ There have been 10 medical wearables of note, such as those marketed to people with asthma with the risk of congestive heart failure and Chronic Obstructive Pulmonary Disease (COPD) as a means to measure pulse, heart rate and oxygen levels in the blood. Popular press publications as well as marketing pieces include articles promoting fitness trackers and other devices as medical devices.

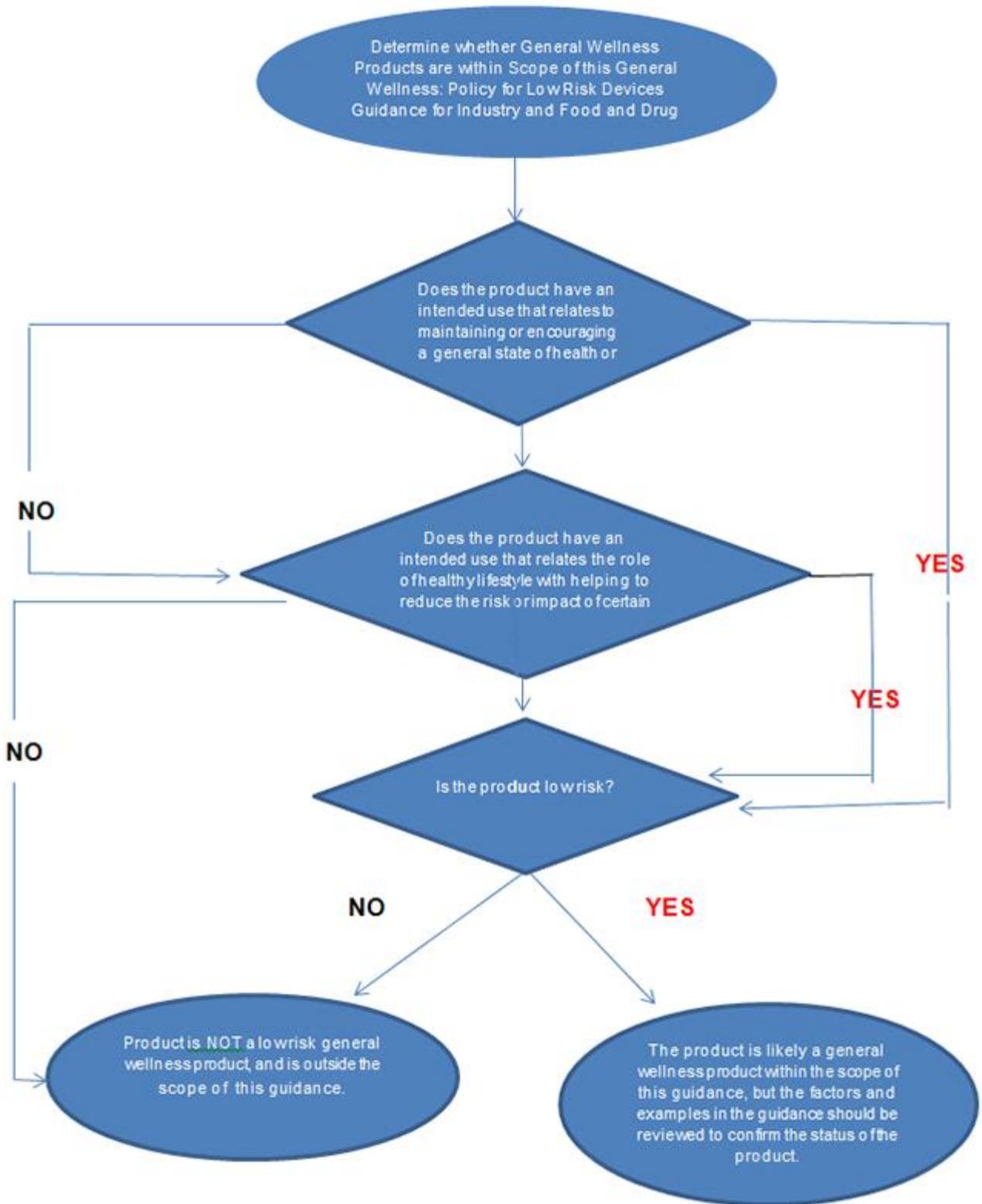
Thus through a combination of ever-growing lists of features related to body functioning and technologies designed for mobile applications, fitness trackers might have migrated from lifestyle to medical devices, depending on how the consumer is using the data generated by them. This expansion of applications also has been promoted to aggressive marketing of these devices specifically for the purpose of patient use related to health and/or illness management. Some see this growing focus on fitness trackers as medical devices as part of a continuation of trends toward patient-centered self-management of health-related conditions.⁹

This expansion (some would say explosion) in wearable medical devices, specifically in fitness trackers, means those involved in the medical device field are compelled to examine and understand the implications of this for research, development, manufacturing and sales. The emergence of fitness trackers as medical devices also comes with various legal challenges, expectations and issues. There are, too, obvious and implicit actions from FDA as well.

What is FDA's official stance on fitness trackers?

FDA has responded to the emergence of wearables including fitness trackers in the midst of legal complaints and challenges. FDA provided draft guidance, General Wellness: Policy for Low Risk Devices, in which the agency describes its current position on regulation of wearable devices such as fitness trackers. The agency suggests it will not directly regulate devices as long as they are not harmful and generally are seen as encouraging positive lifestyle and health habits and activities.¹⁰

Figure 1: Flow Chart for Determining Whether a Product is a General Wellness Device or a Medical Device¹¹



What happens when a lifestyle device is used as a medical device?

In January, 2016, a fraud, class action lawsuit was filed against Fitbit, Inc. over complaints about various models of the FitBit trackers; specifically the Fitbit Blaze, Charge HR and Surge were found to be inaccurate when measuring a user's heart rate during intense physical activity.¹² These results are important as Fitbit widely promotes the PurePulse Heart Rate technology in their advertising. Even prior to the suit's filing, consumers provided complaints stating their Fitbit heart rate monitors were giving unreliable heart rate readings while they were exercising. Some of these complaints came from athletes who tested their heart rates using their specific Fitbit tracker in conjunction with another type of heart monitor.

Tests were conducted, in part, due to the lawsuit, and it was concluded Fitbit's heart rate accuracy during the test was, on average, inaccurate by 20 beats per minute during moderate to high-intensity exercise.¹³ Because these devices are used by athletes as well as others who need to reach or not exceed target heart rates, these inaccurate heart rate readings can lead to serious consequences. Additionally, there are those individuals who may not know they have a cardiac condition, and an inaccurate heart rate reading can put them at risk.

Fitbit also faced in 2016, a proposed class-action lawsuit accusing the company of misrepresenting on their packaging the ability of the sleep-tracking-equipped devices to track users' hours slept, times awakened and sleep quality.¹⁴ The lawsuit cited a 2012 study published in the Sleep Health Journal which cited conclusions including the use of the Fitbit sleep tracker requires specific validation before it can be used to assess disordered populations and or different age groups.

The lawsuit also cited the Fitbit sleep-tracking devices overestimated sleep by 63 minutes per night as compared to the most accurate type of tracking used by sleep scientists, polysomnography.¹⁵ Fitbit also was said to have overestimated sleep by 43 minutes when compared to a less-accurate measure, actigraphy.

As shown here with these brief lawsuit summaries, there are growing pressures on medical device companies as well as FDA to examine arising issues and data. At the present time, medical device firms are well served by engaging in preventative strategies while, at the same time, nurturing a growing market for such devices.

How can manufacturers reduce the legal risks of off-label use?

The following are three options of what manufacturers could do to reduce legal risks of off label use. The first two are actual examples.

- 510(k) Clearance: Camntech Motion Watch and PRO-Diary were cleared as sleep assessment devices in 2014 which means the device was tested by the manufacturer to prove substantial equivalence to another device on the market.¹⁶
- Compliance with 510(k) Cleared Software: Samsung S Health is the software used by the mobile devices cleared through 510(k) with the following indications for use: "The S Health is a mobile application intended for use in home to help people in reviewing and monitoring vital signs, such as non-invasive blood pressure, blood glucose, weight and other data from optional add-on devices for effective health management. The user also can share the data via sharing functions, including email and Short Message Service (SMS)."¹⁷
- Labeling: Labeling, including disclaimers, indications for use, contraindications and warnings, is the least desirable option simply because labeling does not completely prevent the misuse of any device, nor does it preclude a consumer from filing a lawsuit against a device manufacturer.

Conclusion

As the expanding list of health-related features continues to create a different environment for wearable lifestyle devices, regulatory issues emerge as these devices migrate to medical devices. The concept of "intended use" remains integral for assessing whether or not the fitness tracker and software are functioning as a medical device. While FDA has said it has no plans to regulate the devices as long as their use does not present harm, the question remains how might FDA guidelines change as devices shift to increasingly medical device functions? How can manufacturers reduce the legal risks of off-label use if the space between lifestyle device and medical device becomes increasingly cloudy? It is incumbent on manufacturers to keep their eyes fixed on the horizon and be diligent for changes in the regulatory "pulse" regarding these wearable devices.

References

1. US Department of Health and Human Services (HHS). Summary of the HIPAA Privacy Rule. HHS website. <https://www.hhs.gov/hipaa/for-professionals/privacy/laws-regulations/index.html?language=es>. Accessed 10 January 2017.

2. "What is a Medical Device?" 28 December 2015. FDA website. <http://www.fda.gov/AboutFDA/Transparency/Basics/ucm211822.htm>. Accessed 9 January 2017.
3. Center for Devices and Radiological Health (CDRH). Determination of Intended Use for 510(k) Devices; Guidance for Industry and CDRH Staff (Update to K98-1). FDA website. <http://www.fda.gov/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm082162.htm>. Accessed 11 January 2017.
4. "Are Fitness Trackers fit for Security?" *Science Daily*. 9 September 2016. <https://www.sciencedaily.com/releases/2016/09/160909095120.htm>. Accessed 9 January 2017.
5. Garziano, B. "Fossil's Stylist Fitness Trackers Arrive September 26 for \$175." *CNET Magazine*. August 2016. <https://www.cnet.com/news/fossils-stylish-fitness-trackers-arrive-sept-26-for-175/>. Accessed 9 January 2017.
6. Heater, B. "TomTom has Three new Fitness Trackers for IFA." 1 September 2016. TechCrunch website. <https://techcrunch.com/2016/09/01/tomtom/>. Accessed 9 January 2017.
7. Op cit 2.
8. Kawamoto, D. "Ten Wearable-Medical Devices to Improve Patients' Lives." *Information Week*. 12 January 2016. http://www.informationweek.com/healthcare/mobile-and-wireless/10-medical-device-wearables-to-improve-patients-lives/d/d-id/1323544?image_number=10. Accessed 9 January 2017.
9. Chaiuzzi, E., Rodarte, C, and DasMahapatra, P. "Patient-Centered Activity Monitoring in the Self-Management of Chronic Health Conditions." 2015. *BMC Med*, 13, 77.
10. Lecher, C. "The FDA Doesn't Want to Regulate Wearables and Device Makers Want to Keep it That way." *The Verge*. 25 June 2015. <http://www.theverge.com/2015/6/24/8836049/fda-regulation-health-trackers-wearables-fitbit>. Accessed 9 January 2017.
11. Center for Devices and Radiological Health (CDRH). General Wellness: Policy for Low Risk Devices Guidance for Industry and Food and Drug Administration Staff. 29 July 2016. FDA website. http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM429674.pdf?source=govdelivery&utm_medium=email&utm_source=govdelivery. Accessed 9 January 2017.
12. Makortoff, K. "Study Claims FitBit Trackers are 'Highly Inaccurate.'" CNBC website. 23 May 2016. <http://www.cnbc.com/2016/05/23/study-shows-fitbit-trackers-highly-inaccurate.html>. Accessed 9 January 2017.
13. Ibid.
14. Charara, S. "Judge Orders FitBit to Answer Sleep Tracking law Suit Claim. Wareable website. 20 July 2016. <http://www.wareable.com/fitbit/fitbit-sleep-tracking-lawsuit-2016>. Accessed 9 January 2017.
15. Ibid.
16. Camntech Motion Watch and PRO-Diary. 510(K) Summary. http://www.accessdata.fda.gov/cdrh_docs/pdf13/K132764.pdf. Accessed 9 January 2017.
17. Samsung S Heath. 510(K) Summary. http://www.accessdata.fda.gov/cdrh_docs/pdf13/K132148.pdf. Accessed 9 January 2017.

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